



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/797,449

03/10/2004

Thomas A. Osborne

1-37213

4445

42715 7590 12/22/2006
DUNLAP, CODDING & ROGERS, P.C.
P.O. BOX 16370
OKLAHOMA CITY, OK 73113

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

12/22/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

26P

Office Action Summary	Application No. 10/797,449	Applicant(s) OSBORNE ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 16-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/14/04, 8/27/04, 7/25/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>Attachment 1, 2</u> |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species:

Species 1: disclosed on pg.16, lines 8-10, opening defined between leaflet edge and frame generally seen in figs.4-6, 8, 9, and 13-15.

Species 2: disclosed on pg.17, lines 8-12, opening defined entirely by leaflet, seen generally in figs.7, 10, 11, 12, 17A-17D, 20A-20D, and 21-23.

Species 3: disclosed on pg.20, lines 18-31, opening defined by a flap, seen generally in figs.18 and 19A-19F.

The species are independent or distinct because they define structurally different types of openings (frame opening, leaflet hole, leaflet flap) that all perform the same function, allowing retrograde flow.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

Art Unit: 3738

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Matthew Buchanan (Registration No. 47,459) on December 13, 2006 a provisional election was made with traverse to prosecute the invention of species 1, claims 1-11 and 13-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12 and 16-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 each recite the limitation "the total open area" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 101

Art Unit: 3738

Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claiming a comparison to a portion of the body is non-statutory subject matter. Claims 9-11 each recite, "opening is less than ..of the cross-sectional area of said body vessel". Applicant has compared the device directly to the body vessel. It is suggested to change the above to recite, --the opening is sized (or configured) to be less than ...of a cross-sectional area of said body vessel--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-9, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Duran et al. (US 7,125,418 B2). Duran discloses a medical device (fig.6, 8, 11A, 11B) comprising a radially expandable support frame (stent 27+28+23; OR 17+18+23), at least one leaflet (located between commissures 20 in figs.) having a first edge (bottom inflow edge) attached to the support frame (at 17) and a second edge (top outflow edge) free from the frame (at 20a), the leaflet movable from a first position (seen open in figs.7a, 8b, 9) permitting flow in a first direction and a second position (seen in figs.11a, 8c) substantially preventing flow in a second direction, a portion of the frame (28) and second edge (20a) cooperatively defining an opening (seen in figs.11a, 9) that permits a controlled amount of flow in the second direction (see

attachment 1). Duran discloses the frame to be same expanding Ni-Ti (col.5, lines 105, 64-68), and the leaflet to be bioremodelable (col.3, lines 36-42, 58-61). Duran discloses the leaflet attaching to the frame by a suture (17, 18), the device comprising two leaflets (see figs) and the opening to cover less area than the total vessel cross section (seen in fig. 11a).

Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Moll et al. (US 6,287,334 B1, cited in IDS). Moll discloses a medical device comprising a radially expandable support frame (10), at least one leaflet (12) having a first edge attached to the support frame (along 8) and a second edge free from the frame (free edge of 12, see attachment 2), the leaflet movable from a first position (fig.5) permitting flow in a first direction and a second position (fig.6) substantially preventing flow in a second direction, a portion of the frame (10) and second edge (free edge of 12) cooperatively defining an opening (near 16) that permits a controlled amount of flow in the second direction (a controlled amount fill pocket; col.1 line 62- col.2 line 7). Moll discloses the frame to be same expanding (col.2, lines 19-26; fig.3, 4). Moll discloses the leaflet (12) attaching to the frame (10) by a suture (stitching seen in fig.1), the device comprising two leaflets and the opening to cover less area than the total vessel cross section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 10, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran et al. (US 7,125,418 B2). Referring to claims 5, 6, 14, and 15, Duran discloses a medical device comprising tissue valve leaflets (col.3, lines 36-42, 58-61), however does not specifically disclose ECM or submucosa (particular types of tissue). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed materials for the leaflets, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Referring to claims 10 and 11, Duran has shown an opening formed between the frame and leaflet edge when in the closed position, opening only a portion of the vessel cross-section (see fig. 11a for example), however is silent to mention an exact percentage of openage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent open area claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 3-6, 10, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1). Referring to claims 3-6 and 13-15, Moll discloses a medical device (fig.1) having all the structural features claimed (see above), however does not disclose the exact materials claimed for the frame and leaflet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed materials for the leaflets and frame, since it has been held to be within the general skill of a worker in the art to

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Referring to claims 10 and 11, Moll has shown an opening formed between the frame and leaflet edge when in the closed position, opening only a portion of the vessel cross-section (16; fig.1), however is silent to mention an exact percentage of openage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent open area claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller

**BRUCE SNOW**
PRIMARY EXAMINER

Attachment #1 (marked up)

U.S. Patent

Oct. 24, 2006

Sheet 4 of 5

US 7,125,418 B2

FIG. 9

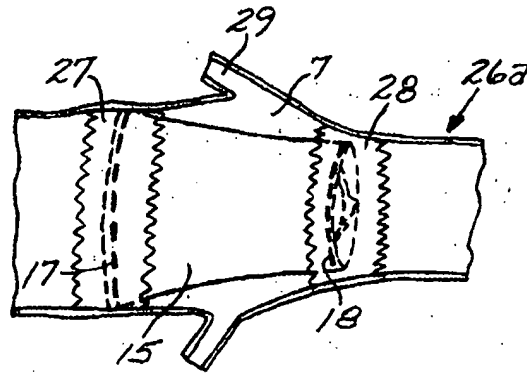


FIG. 10

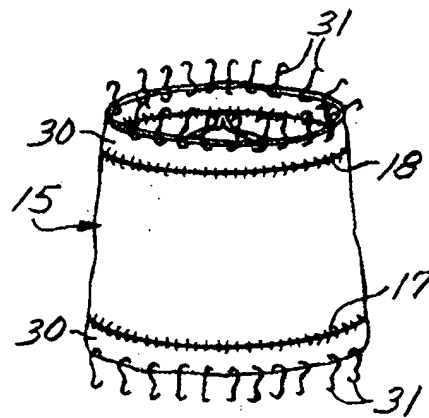


FIG. 11A

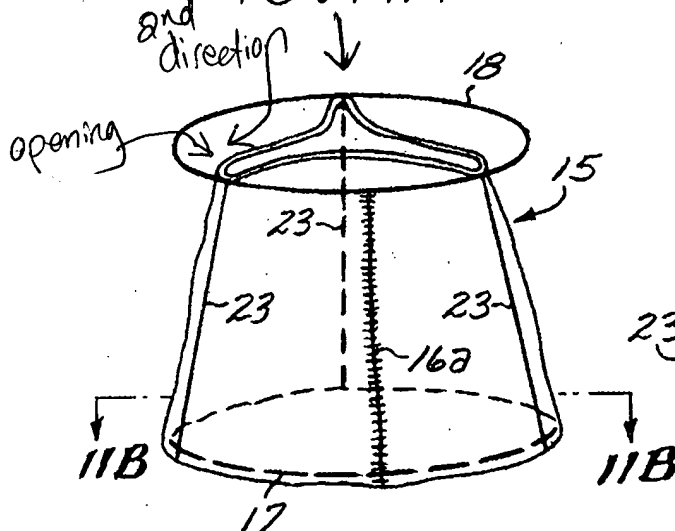
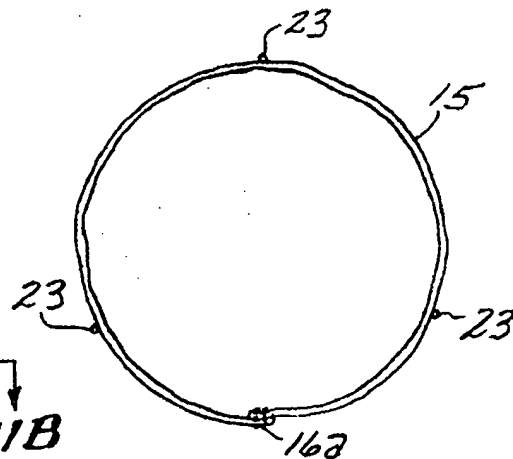


FIG. 11B



↑ 1st direction

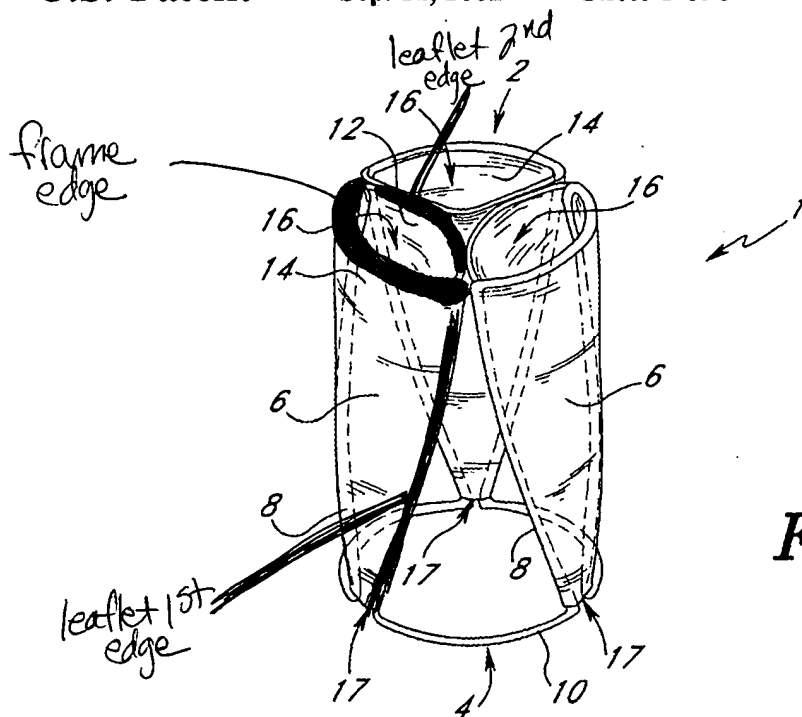


FIG. 1

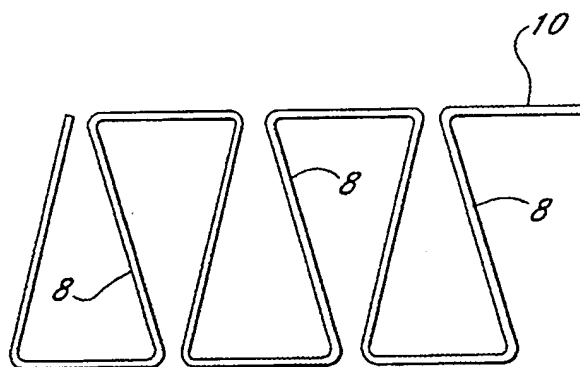


FIG. 2

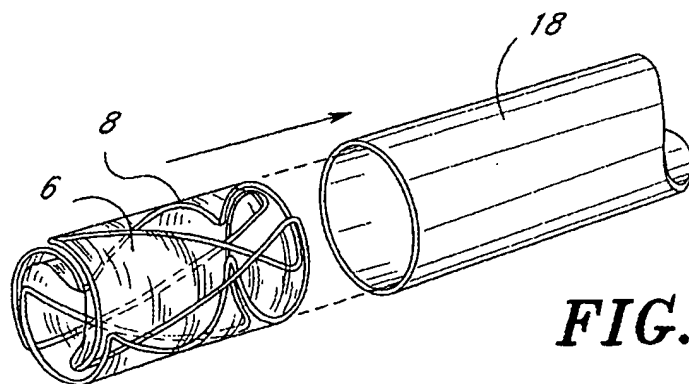


FIG. 3